Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE office on of information unless it contains a valid OMB control number.

U.S. Palent and Trademark Collect. On the Comment of the Parent of Trademark Collect. On the Comment of the Parent of the Parent

Substitute for f	abstitute for form 1449A/PTO			Complete if Known		
	31 1443.21 10			Application Number	Not Yet Assigned	
INF	ORMATIO	N DIS	CLOSURE	Filing Date S	September 8, 2003	
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Lewis H. Lambert, Jr.	
				Art Unit	Not Yet Assigned	
	(use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	4	Attorney Docket Number	29715/33202B	

			บ.ร. เ	PATENT DOCUMENTS			
*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
27.	A01	5,032,574	7/16/91	Wilde et al.	514	12	
1	A02	5,089,274	2/18/92	Marra et al.	424	534	
	A03	5,171,739	2/15/92	Scott	514	12	
	A04	5,198,541	3/3/93	Elsbach et al.	435	69.1	
	A05	5,234,912	8/10/93	Marra et al.	514	12	
	A06	5,308,834	5/3/94	Scott et al.	514	12	
	A07	5,334,584	8/2/94	Scott et al.	514	12	
1//	A08	5,348,942	9/20/94	Little, II et al.	514	12	
—	A09	5,763,567	6/9/98	Little	530	300	

			FOREIGN PATE	NT DOCUMENT	S		 	
*Examiner Initials		Document Publication Number Date		Country	Class	Subclas s	Translation	
							Yes	No
MT.	B01	WO 88/06038	08/25/88	WIPO		-		
	B02	WO 92/03535	3/5/92	WIPO				
	B03	WO 92/09621	6/11/92	WIPO				
	B04	WO 93/05797	4/4/93	WIPO				
	B05	WO 93/06228	4/1/93	WIPO				
	B06	WO 93/23434	11/25/93	WIPO				
	B07	WO 93/23540	11/25/93	WIPO				
	B08	WO 94/17819	8/18/94	WIPO				
	B09	WO 94/18323	8/18/94	WIPO				***************************************
	B10	WO 94/20128	9/15/94	WIPO				
	B11	WO 94/20129	9/15/94	WIPO				
	B12	WO 92/14155	8/20/92	WIPO				********
V	B13	WO 97/42966	11/20/97	WIPO				
V	B14	WO 97/44056	11/27/97	WIPO				

Examiner / //	Date	0 (00 0 (
Signature / Uh (-)	Considered	06,02.05

^{*}EXAMINER: Initial Treference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ³ See attached Kinds Codes of USPTO Patent Documents at www.usgto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO		Complete if Known		
-	Application Number	Not Yet Assigned		
INFORMATION DISCLOSURE	Filing Date	Sept mb r 8, 2003		
STATEMENT BY APPLICANT	First Named Inventor	Lewis H. Lambert, Jr.		
	Art Unit	Not Yet Assigned		
(use as many sheets as necessary)	Examiner Name	Not Yet Assigned		
Sheet 2 of 4	Attorney Docket Number	29715/33202B		

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
Not included	C01	Beaman et al., "Cytokines, Toxoplasma and Intracellular Parasitism", Immun. Rev. 127: 97-117 (1992)
Submitted	C02	Brown et al., "Azithromycin, Rifabutin, and Rifapentine for Treatment and Prophylaxis of Mycobacterium avium Complex in Rats Treated with Cyclosporine", Antimicrob. Agents and Chemother., 37(3): 398-402 (March 1993)
	C03	Buddemeyer et al., "Automatic Quantitative Radiometric Assay of Bacterial Metabolism", Clin. Chem., 22(9): 1459-1464 (1976)
	C04	Chaterjee et al., "Structural Basis of Capacity of Lipoarabinomannan to Induce Secretion of Tumor Necrosis Factor", Infect. and Immun., 60(3): 1249-1253 (March 1992)
	C05	Collins, "Antituberculous Immunity: New Solutions to an Old Problem", Rev. of Infect. Dis., 13(5): 940-950 (1991)
	C06	Cornforth et al., "Antituberculous Effect of Certain Surface-Active Polyoxytethylene Ethers in Mice", Nature, 168: 150-153 (July 28, 1951)
	C07	Davidson and Le, "Drug Treatment of Tuberculosis - 1992", Drugs, 43(5):651-673 (1992)
	C08	Elsbach et al., "Separation and Purification of a Potent BPI Protein and a Closely Ass. Phospholipase A₂ from Rabbit Polymorphonuclear Leukocytes", <i>J. Biol. Chem.</i> , 254: 11000-11009 (November 10, 1979)
	C09	Franzblau and Hastings, "Rapid in vitro Metabolic Screen for Antileprosy Compounds", Antimicrobial Agents and Chemo., 31(5): 780-783 (May 1987)
	C10	Friedland, "Cytokines, Phagocytosis, and Mycobacterium tuberculosis", Lymphokine and Cytokine Research, 12(2): 127-133 (November 2, 1993)
	C11	Gazzano-Santoro et al., "High-Affinity Binding of the BPI Protein and a Recombinant Amino- Terminal Fragment to the Lipid A Region of Lipopolysaccharide", <i>Infect. Immun., 60</i> : 4754- 4761 (November 1992)
	C12	Gray et al., "Cloning of the cDNA of a Human Neutrophil Bactericidal Protein", J. Biol. Chem., 264: 9505-9509 (June 5, 1989)
	C13	Hastings et al., "Leprosy", Clin. Micro. Reviews, 1: 330-348 (July 1988)
	C14	Hunter et al., "Structure and Antigenicity of the Phosphorylated Lipopolysaccharide Antigens from the Leprosy and Tubercle Bacilli", J. Biol. Chem., 261: 12345-12351 (September 1986)
	C15	Inderlied, "Antimycobacterial Agents: In Vitro Susceptibility Testing, Spectrums of Activity, Mechanisms of Action and Resistance, and Assays for Activity in Biological Fluids", in Antibiotics in Laboratory Medicine, pp. 134-197, 3rd ed., (V. Lorian ed., The Williams & Wilkins Co., Baltimore) (1991)
	C16	Kelly et al., "Role of Bactericidal/Permeability Increasing Protein (BPI) in the Management of Gram Negative Pneumonia," Presented At the Annual Meeting of the Society of Univ. Surgeons, Feb. 10-14, 1993 (abstract)
	C17	Kirchheimer and Storrs, "Attempts to Establish the Armadillo (Dasypus novemcinctus Linn.) as a Model for the Study of Leprosy", Int. J. Lepr., 39(3): 693-702 (July-September 1971)
V	C18	Lalande et al., "Powerful Bactericidal Activity of Sparfloxacin (AT-4140) against Mycobacterium

<u> </u>			
Examiner	Date		
	Date	0/2 - 0/2	
Signature / / C	Considered	00102.53	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁴ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE of information unless it contains a valid OMB control number.

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERC

Substitute fo	or form 1449A/PTO			Complete if Known		
				Application Number	Not Yet Assigned	
INI	FORMATION	DIS	CLOSURE	Filing Date	September 8, 2003	
ST	ATEMENT E	BY A	PPLICANT	First Named Inventor	Lewis H. Lambert, Jr.	
				Art Unit	Not Yet Assigned	
	(use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	3	of	4	Attorney Docket Number	29715/33202B	

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
		tuberculosis in Mice", Antimicrob. Agents and Chemo., 37(3): 407-413 (March 1993)
Not included/	C19	Little et al., "Functional Domains of Recombinant Bactericidal/Permeability Increasing Protein (rBPl ₂₃)", <i>J. Biol. Chem.</i> , 269(3):1865-1872 (January 21, 1994)
Submitted	C20	Levy et al., "Antibacterial I5-kDA Protein Isoforms (p15s) are Members of a Novel Family of Leukocyte Proteins", J. Biol. Chem., 268(8):6038-6083 (1993)
	C21	Mittal et al., "Rapid, Radiolabeled-Microculture Method That Uses Macrophages for In Vitro Evaluation of Mycobacterium leprae Viability and Drug Susceptibility", J. Clin. Microbiol., 17(4): 704-707 (April 1983)
	C22	Ooi et al., "Endotoxin-neutralizing Properties of the 25 kD N-Terminal Fragment and a Newly Isolated 30 kD C-Terminal Fragment of the 55-60 kD Bactericidal/Permeability-Increasing Protein of Human Neutrophils", <i>J. Exp. Med.</i> , 174: 649-655 (September 1991)
	C23	Ooi et al., "Isolation of Two Isoforms of a Novel 15-kDa Protein from Rabbit Polymorphonuclear Leukocytes that Modulate the Antibacterial Actions of Other Leukocyte Proteins", J. Biol. Chem., 265(26):15956-15962 (September 15, 1990)
	C24	Orme et al., "Inhibition of Growth of Mycobacterium avium in Murine and Human Mononuclear Phagocytes by Migration Inhibitory Factor", Infect. and Immun. 61(1): 338-342 (January 1993)
	C25	Otterlei et al., "Similar Mechanisms of Action of Defined Polysaccharide and Lipopolysaccharides: Characterization of Binding and Tumor Necrosis Factor Alpha Induction", Infect. and Immunity, 61(5): 1917-1925 (May 1993)
	C26	Portaels et al., "Cultivable Mycobacteria Isolated From Organs of Armadillos Uninoculated and Inoculated with Mycobacterium Leprae", Ann. Inst. Pasteur/Microbiol., 136: 181-190 (1985)
	C27	Rastogi, "Killing Intracellular Mycobacteria in in vitro Macrophage Systems:What May Be the Role of Known Host Microbicidal Mechanisms?", Res. Microbiol., 141(2): 217-230 (1990)
	C28	Roberts et al., "Evaluation of the BACTEC Radiometric Method for Recovery of Mycobacteria and Drug Susceptibility Testing of <i>Mycobacterium tuberculosis</i> from Acid-Fast Smear-Positive Specimens", <i>J. of Clin. Microbiol.</i> , 18(3): 689-696 (September 1983)
	C29	Schwab and Mandell, "The Importance of Penetration of Antimicrobial Agents into Cells", Infect. Dis. Clinics of North America, 3(3): 461-467 (September 1989)
	C30	Shah et al., "A Rapid Radiometric Method for Detection of M. Tuberculosis: Optimization of Experimental Conditions", Int. J. Nucl. Med. Biol., 11(3/4): 283-286 (1984)
	C31	Shepard, "The Experimental Disease that Follows the Injection of Human Leprosy Bacilli into Foot-Pads of Mice", J. Exp. Med., 112: 445-454 (1960)
	C32	Shepard and Chang, "Effect of Several Anti-Leprosy Drugs on Multiplication of Human Leprosy Bacilli in Foot-Pads of Mice", <i>Proc. Soc. Exp. Biol. Med.</i> , 109: 636-638 (1962)
	C33	Shepard and McRae, "A Method for Counting Acid-fast Bacteria", Int. J. Lepr., 36: 78-82 (1968)
	C34	Shepard et al., "Experimental Chemotherapy in leprosy," Bull. World Health Organ., 53: 425-433 (1976)
Ψ	C35	Sibley and Krahenbuhl, "Defective Activation of Granuloma Macrophages From

Examiner //		Date	
Signature	, /		06 02.05
Language Constitution of the Constitution of t		Considered	01-4-0
	/		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. ¹Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁶For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁶Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002,OMB 0651-0031 U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMER Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for f	orm 1449A/PTO			Complete if Known		
Outsingle for t	J. 1443241 10			Application Number	Not Yet Assigned	· · · · · · · · · · · · · · · · · · ·
INF	ORMATIC	ON DIS	SCLOSURE	Filing Date	September 8, 2003	
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Lewis H. Lambert, Jr.	
				Art Unit	Not Yet Assigned	
	(use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	4	of	4	Attorney Docket Number	29715/33202B	

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
		Mycobacterium leprae-Infected Nude Mice", J. of Leukocyte. Biol., 43: 60-66 (1988)
Not	C36	Sibley and Krahenbuhl, "Induction of Unresponsiveness to Gamma interferon in Macrophages Infected with Mycobacterium leprae", Infect. and Immun., 56(8): 1912-1919 (August 1988)
Submitted	027	Sibley and Krahenbuhl, "Mycobacterium leprae-Burdened Macrophages Are Refractory to Activation by Gamma Interferon", Infect. and Immun., 55(2): 446-450 ((February 1987)
	C38	Sibley et al., "Inhibition of Interferon-Gamma-Mediated Activation in Mouse Macrophages Treated With Lipoarabinomannan", Clin. Exp. Immunol., 80(1),: 141-148 (1990)
	C39	Sibley et al., "Intracellular Fate of Mycobacterium leprae in Normal Activated Mouse Macrophages", Infect. and Immun., 55(3): 680-685 (March 1987)
	C40	Sibley et al., "Mycobacterial lipoarabinomannan Inhibits Gamma Interferon-Mediated Act. of Macrophages", Infect. and Immun., 56(5): 1232-1236 (May 1988)
	C41	van den Broek, "Activity of Antibiotics against Microorganisms Ingested by Mononuclear Phagocytes", Eur. J. Clin. Microbiol. Infect. Dis., 10(2): 114-118 (February 1991)
	C42	Weiss and Olsson, "Cellular and Subcellular Localization of the BPI Protein of Neutrophils", Blood, 69: 652-659 (February 1987)
	C43	Weiss et al., "Human BPI Protein and a Recombinant NH ₂ -Terminal Fragment Cause Killing of Serum-resistant Gram-negative Bacteria in Whole Blood and Inhibit Tumor Necrosis Factor Release Induced by the Bacteria", <i>J. Clin. Invest.</i> , 90: 1122-1130 (September 1992)
	C44	Kelly et al., "Role of Bactericidal/Permeability-Increasing Protein in the Treatment of Gram-Negative Pneumonia", Surgery, 144(2):140-146 (August 1993)
V	C45	Edgington, "How Sweet It Is: Selectin-Mediating Drugs", Bio/Technology, 10:383- 386, 388, 389 (1992)

Examiner Signature	on to		Date Considered	06.62.05	
		-,			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant